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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------|------------------------|
| 10/757,047 | 01/14/2004 | Heinrich Kladders | 1/1449 | 4842 |
| 28501 7590 10/04/2007 MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368 | | | EXAMINER ALI, SHUMAYA B | |
| | | | ART UNIT 3771 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-----------------|-----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/757,047 | KLADDERS ET AL. | |
| | Examiner | Art Unit | |
| | Shumaya B. Ali | 3771 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. US 5,152,284.

As to claim 1, Valentini teaches a method for administering a composition by inhalation comprising administering to a patient the composition, contained in a capsule (fig.1, 22) comprising a longitudinal axis and a transverse axis which is shorter in relation to the longitudinal axis (see fig.1) and which is intended to accommodate the composition in the form of a powder (col.1, lines 40-50), in a powder inhaler (fig.1, 10), wherein the features forming the outer contour of the capsule are symmetrical with respect to a transverse plane which bisects the longitudinal axis (see capsule 12 in fig.1), the following features being excluded from the conditions of symmetry: fine structures of the seams which are produced by the sealing of the seams of the individual parts of the capsule, and/or elements formed on the capsule surface which are smaller than 0.1 mm, and/or angles of taper up to 5° (see fig.1, 12). Valentini however lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps as cited for claim 1. Thus, the method steps as cited in claim 1 would have been obvious result of using the apparatus of Valentini.

As to claim 2, Valentini teaches the method according to claim 1 wherein the inhaler is a Bernoulli inhaler. Applicant on page 3, lines 26-28 of his disclosure states that powder inhaler operate by the Bernoulli effect, which behave identically irrespective of their positioning. Since Valentini also teaches a powder inhaler, the inhaler of Valentini is considered Bernoulli inhaler.

As to claim 3, Valentini teaches the method according to claim 1 wherein features located on the outer contour of the capsule surface and forming a symmetrical pair may have a tolerance and inaccuracy deviating from the symmetry of 0.15 mm in each case (see fig.1, 22).

As to claim 4, Valentini teaches the method according to claim 1 wherein the capsule has elevations on its outer surface (see labeled fig.1, attachment below).

As to claim 5, Valentini teaches the method according to claim 1 wherein the capsule has no elevations (fig.1 depicts that capsule 22 has no elevations in at least a portion of its outer surface).

As to claim 6, Valentini teaches the method according to claim 1 wherein the capsule consists of two parts (see labeled fig.1, attached below), which can be pushed telescopically one inside the other along the longitudinal axis (fig. 1 of Valentini clearly depicts two parts of capsule (22) pushed telescopically).

As to claim 7, Valentini teaches the method according to claim 1 wherein the capsule has a cylindrical outer contour (see fig.1, 22).

As to claim 8, Valentini lacks the explicit teaching of wherein the capsule has tapering sealed ends. However, it should be noted that Valentini teaches a capsule where an upper and lower parts are sealingly engaged (see labeled fig.1, attached below) by the nature of upper and lower parts' diameter sizes. The narrower diameter upper part (part I, see labeled fig.1, attached below) of capsule 22 is considered tapering sealed end. Thus Valentini teaches wherein the capsule has tapering sealed ends.

As to claim 9, Valentini teaches the method according to claim 6 wherein the seam created between the two parts of the closed capsule is offset from the center by 0 to 12% of the outer longitudinal length (see labeled fig.1, attached below).

As to claim 10, Valentini teaches the method according to claim 1 wherein the capsule comprises a member of the D- symmetry group in terms of its outer contour, irrespective of the seam between the two parts of the capsule and irrespective of any manufacturing tolerances (see labeled fig.1, attached below).

As to claim 17, Valentini teaches a capsule (fig.1, 22) for holding a pharmaceutical composition which, in the closed state, has a longitudinal axis and a transverse axis which is shorter in relation to the longitudinal axis (see fig.1, 22) and which consists of two parts which can be pushed telescopically inside one another along the longitudinal axis (see labeled fig.1, attached below), wherein the features forming the outer contour of the closed capsule are symmetrical with respect to a transverse plane which bisects the longitudinal axis, the following features being excluded from the conditions of symmetry (see labeled fig.1, attached below): fine structures of the seams which are produced by the sealing of the seams of the individual parts of the capsule, and/or elements formed on the capsule surface which are smaller than 0.1 mm, and/or angles of taper up to 5° (see "elevation" in the labeled fig.1, attached below).

As to claim 18, Valentini teaches the capsule according to claim 17 wherein the seam created between the two parts when the capsule is closed is offset from the center by 0 to 12% of the outer longitudinal length (see labeled fig.1, attached below).

As to claim 19, Valentini teaches the method according to claim 1 wherein the capsule comprises a member of the D- symmetry group in terms of its outer contour, irrespective of the seam between the two parts of the capsule and irrespective of any manufacturing tolerances (see labeled fig.1, attached below).

As to claim 20, Valentini teaches the capsule according to claim 17 wherein features located on the outer contour (see labeled fig.1, attached below) of the capsule surface and forming a symmetrical pair may have a tolerance and inaccuracy deviating from the symmetry of 0.15 mm in each case (see labeled fig.1, attached below).

**Claims 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over
Hochrainer et al. US 5,947,118**

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

As to claim 11, Hochrainer in figure 6 teaches the method according to claim 1 wherein the inhaler comprises two housing parts, an upper housing part (13) which is connected to a mouthpiece (12), and a lower housing part (6) with at least one capsule chamber (9), the capsule chamber(s) having an air inlet opening (14), and an air outlet opening connected to the mouthpiece via a connection capable of conducting an aerosol, powder or liquid (col.3, lines 1-17). Hochrainer however lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps as cited for claim 11. Thus, the

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method steps as cited in claim 11 would have been obvious result of using the apparatus of Hochrainer.

As to claim 12, Hochrainer teaches the method according to claim 11 wherein the capsule chamber has a cross section 1.1 to 2.5 times as great as the capsule diameter and a length 1.02 to 2 times the length of the capsule (see three capsules depicted in figure 6).

As to claim 13, Hochrainer teaches the method according to claim 11 wherein the inhaler has a cutting device (see "needles" in col.3, lines 5-7) comprising at least two sharp spikes and/or cutters (see "needles" in col.3, lines 5-7), the spikes and/or cutters being capable of breaching the capsule chamber(s) (col.3, lines 7-10).

As to claim 14, Hochrainer teaches the method according to claim 11 wherein the inhaler comprises: a) a cup-shaped lower part open at the top (6), b) a plate (8) which covers the opening of the lower part and perpendicularly to which is formed a pharmaceutical capsule chamber of the type described above (see capsules depicted in fig.6), a button (10) movable counter to a spring (11) on the capsule chamber, a cutting device (see "needles" in col.3, lines 5-10) comprising two sharp spikes or cutters for opening the capsule (col.3, lines 5-10), c) an upper part (13) with the mouthpiece which is connected to the capsule chamber so as to be able to convey a powder, aerosol or liquid, and d) a lid (15), the elements a), b) c) and d) being joined together by a common hinge element (see hinge apertures on the body of cap 15 and lower part 6 in fig.6) such that they can be moved back and forth relative to one another.

As to claim 15, Hochrainer teaches the method according to claim 11 wherein inhaler contains a magazine of capsule chambers (1).

As to claim 16, Hochrainer teaches an inhaler (fig.6) for administering a composition comprising an upper housing part (13) which is connected to a mouthpiece (12) and a lower housing part (6) with at least one capsule chamber (9), the capsule chamber(s) having an air inlet opening (14), and an air outlet opening (opening through the mouthpiece) connected to the mouthpiece, wherein at least one capsule chamber is capable of accommodating a capsule having a longitudinal axis and a transverse axis which is shorter in relation to the longitudinal axis wherein a composition is placed (see fig.6), the features forming the outer contour are symmetrical with respect to a transverse plane that bisects the longitudinal axis, the following features being excluded from the conditions of symmetry: fine structures of the seams which are produced by the sealing of the seams of the individual parts of the pharmaceutical capsule, and/or elements formed on the capsule surface which are smaller than 0.1 mm, and/or -angles of taper up to 5° (see fig.6). Hochrainer however lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps as cited for claim 16. Thus, the method steps as cited in claim 16 would have been obvious result of using the apparatus of Hochrainer.

Response to Arguments

Applicant's arguments filed 7/16/07 have been fully considered but they are not persuasive. On page 7, lines 19 and 20 Applicant argues that Examiner's allegation that the capsule elevation (the discontinuity) in Valentini is a taper up to 5 degree as claimed is erroneous. This argument however is not well taken because claims requires certain feature being "excluded" from the conditions of symmetry, and limitation of "5" degree is one of them. If

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applicant believes that Valentini does not teach "5 degree" then Valentini meets the claimed limitation.

On page 8, lines 12-14 Applicant argues that Hochrainer lacks capsule that are symmetrical with respect to a transverse plane. Again further argues that Hochrainer lacks "elements smaller than 0.1 mm, and/or angles of taper up to 5 degrees. Once again, structures e which applicant argues for are recited as "excluded" structure of the claimed invention.

Thus, rejection as cited in the previous office action is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

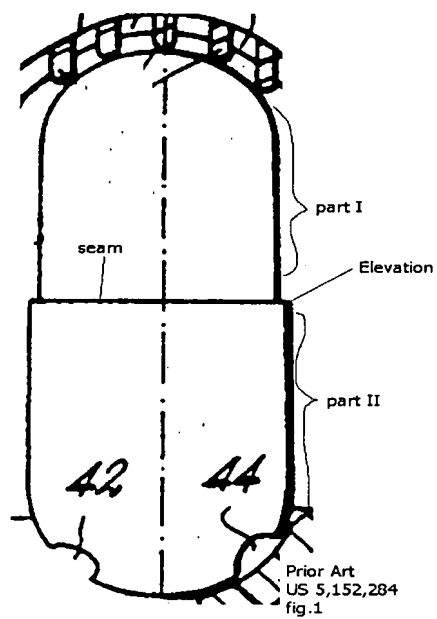
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


TEENA MITCHELL
PRIMARY EXAMINER


Shumaya B. Ali
Examiner
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10/1/08